Summary of External Peer Review and Public Comments and Disposition

This document summarizes the public and external peer review comments that the EPA's Office of Pollution Prevention and Toxics (OPPT) received for the draft work plan risk assessment for dichloromethane (DCM). It also provides EPA/OPPT's response to the comments received from the public and the peer review panel.

EPA/OPPT appreciates the valuable input provided by the public and peer review panel. The input resulted in numerous revisions to the risk assessment.

Peer review charge questions[1] are used to categorize the peer review and public comments into specific issues related to the five main themes.

- General Issues on the Risk Assessment Document
- Occupational Exposure
- Consumer Exposure
- Hazard and Dose-Response Assessments
- Risk Characterization

A separate section called *Other Public Comments* organizes the response to those public comments that are unrelated to the main themes listed above.

[1] These are the questions that EPA/OPPT submitted to the panel to guide the peer review process.

General Issues on the Risk Assessment Document

Charge question 1-1: Please comment on whether the risk assessment provides a clear and logical summary of EPA's analysis. Please provide specific suggestions for improving the clarity and transparency of the risk assessment document.

Charge question 1-2: Please comment on whether appropriate background information is provided and accurately characterized. Please provide any other relevant literature, reports, or data that would be useful to support the risk assessment.

#	Summary of Peer Review and Public Comments for Specific Issues Related to Charge Questions 1-1 and 1-2	EPA/OPPT Response
1	Document is not clear about the purpose of the risk assessment. The document would be substantially improved if a clear statement was made regarding the audience and utility of the report.	EPA/OPPT has made significant revisions to the DCM risk assessment to improve the clarity of the assessment. In addition, the purpose and audience have been described in *section 1.1* of the final DCM risk assessment.
2	EPA/OPPT did not assess dermal exposure to DCM for occupational and residential scenarios. Why is dermal exposure considered less significant than inhalation exposure? By not including dermal exposure in the exposure assessment, exposure is likely to be underestimated.	EPA/OPPT recognizes that dermal exposure to highly volatile materials such as DCM can occur. However, based on the physical-chemical properties of DCM and the scenarios described in this assessment, EPA/OPPT believes that inhalation is the main exposure pathway when respiratory protection is not used. This assessment may underestimate total exposures resulting from the uses of DCM due to this assumption. Currently, there is no DCM PBPK model with a dermal component that would allow for route to route extrao0plation and aggregate exposure estimation for all routes. There is also a paucity of exposure information that would be needed for inputs into this extended modeling effort. Thus, we agree this assessment likely underestimates risks resulting from the uses of DCM being assessed. This has been acknowledged in the *Executive Summary*, *section 1.3.2* and the uncertainty and data limitations section of the assessment *3.5.1*.
3	EPA/OPPT's small shop focus may not be warranted. For example, larger shops may have risks. The assumption that the small shops have exposures that are less controlled and monitored than those seen in large-scale industrial operations is not supported.	EPA/OPPT improved the focus descriptions in the *Executive Summary*, *sections 1.3.3* and *3.1.1* and *Appendices F* and *G*. EPA/OPPT found that there were limited readily available data to support the original assumption and removed the assumption that small shops have < 10 workers. Therefore, even though the interest is for small shops, the occupational exposure analysis retains data and analyses for all industries and shop sizes. EPA/OPPT cannot rule out that any of these industries may have small shops engaging in paint stripping jobs.

		In addition, EPA/OPPT revised the occupational exposure assessment to include a scenario approach that considers the use of respirators to control exposures. *Section 3.1.1* contains information about the occupational scenarios examined in the final DCM risk assessment.
4	The draft DCM risk assessment did not identify all high risk uses of DCM, such as DCM-containing adhesives. Thus, the scope of the assessment should be expanded to include other DCM uses. Also, it should not be assumed that the other DCM uses have lower risks relative to paint stripping. In addition, the assessment did not provide a clear framework to prioritize specific use scenarios.	The final DCM risk assessment focuses on the likely highest exposure use (i.e., paint stripping). Other potential uses of DCM were not the focus of the current assessment. *Section 1.3.1* discusses the factors that EPA/OPPT considered when selecting the use scenarios for this assessment.
5	It was suggested that EPA/OPPT needed to conduct a systematic evaluation of the quality of the studies used to support the DCM risk assessment.	EPA/OPPT revised the assessment to include the following data quality criteria used to evaluate the scientific information supporting the final DCM risk assessment. • *Appendix G* contains descriptions of the data quality criteria used in the occupational exposure assessment. Similar criteria were used for the consumer exposure assessment as acknowledged in *section 3.2.1*. • The bioconcentration and persistence information were assessed according to the criteria set forth in the EPA's New Chemical Premanufacture Notification Program (PMN) (EPA, 1999). • The aquatic toxicity data were evaluated using the criteria set forth in the *TSCA Work Plan Chemicals Methods Document* (EPA, 2012) and the *Classification Criteria for Environmental Toxicity and Fate of Industrial Chemical*s (EPA, 1992). • EPA/OPPT used the U.S. EPA's IRIS assessment for DCM for the chronic hazard and dose-response assessments (EPA, 2011). The DCM IRIS assessment considered the principles set forth by the various risk assessment guidelines issued by the National Research Council and the U.S. EPA (see *Appendix I* of the final DCM risk assessment). • DCM's hazard and dose-response assessments for acute effects were based on the principles set forth by the Standing Operating Procedures for Developing Acute Exposure Guideline Levels (NRC, 2001) and the *Guidelines for Developing Spacecraft Maximum Allowable*

		Concentrations for Space Station Contaminants (NRC, 1992) (see *Appendix I* of the final DCM risk assessment). **References:** EPA (U.S. Environmental Protection Agency). 1999. *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances*. 64 Federal Register 213 (November 4, 1999), pp. 60194-60204. EPA (U.S. Environmental Protection Agency). 2012. *TSCA Work Plan Chemicals: Methods Document*. Office of Pollution Prevention and Toxics, Washington, DC. www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf. EPA (U.S. Environmental Protection Agency). 1992. *Classification Criteria for Environmental Toxicity and Fate of Industrial Chemical*. Office of Pollution Prevention and Toxics, Washington, DC. EPA (U.S. Environmental Protection Agency). 2011. *Toxicological Review of Dichloromethane (Methylene Chloride; CAS No. 75-09-2)*. EPA/635/R-10/003F. Integrated Risk Information System, Office of Research and Development, Washington, DC. http://www.epa.gov/iris/toxreviews/0070tr.pdf. NRC (National Research Council). 2001. *Standing Operating Procedures for Developing Acute Exposure Guideline Levels for Hazardous Chemicals*. National Academy Press, Washington DC. http://www.epa.gov/oppt/aegl/pubs/sop.pdf. NRC (National Research Council). 1992. *Guidelines for Developing Spacecraft Maximum Allowable Concentrations for Space Station Contaminants* National Academy Press, Washington, DC.

6	EPA/OPPT received comments suggesting that the DCM risk assessment should be described as a screening-level risk assessment.	The final DCM risk assessment is not considered a screening-level risk assessment. The occupational exposure assessment was based on DCM air monitoring data collected from relevant industries conducting paint stripping activities. The consumer exposure assessment used EPA's Multi-Chamber Concentration and Exposure Model (MCCEM), which requires data requirements, such as input emission rates and decay rates, which are related to higher tier models. Also, the scenario approach for the consumer and occupational exposure assessment considered central-tendency and upper-end input parameters and assumptions to develop realistic exposure scenarios. In addition, physiologically-based pharmacokinetic (PBPK) modeling was conducted to derive most of the acute and chronic hazard values used in this assessment (i.e., human equivalent concentrations).
7	A peer reviewer noted missing hazard and risk information in the Executive summary.	EPA/OPPT made appropriate revisions or clarifications to the Executive Summary to address the issues that the peer reviewer identified.
8	The draft DCM risk assessment had inconsistent statements about DCM's Global Warming Potential (GWP). Specifically, Table 2-3 listed the lack of GWP as a one of the benefits of DCM. However, the *Environmental Fate* section stated that DCM has been reported as a GWP chemical with a value of 8.7 (~ 8.7 times more heat absorptive than CO_2).	EPA/OPPT made changes to Table 2-3 (*section 2.2.1*) to fix the inconsistency in the final DCM risk assessment.
9	Public comments made the observation that the draft DCM risk assessment did not discuss DCM replacement alternatives.	EPA/OPPT did not discuss the available replacement alternatives in the final DCM risk assessment. Such discussion will take place in the future as part of the risk management activities for DCM.

10	EPA/OPPT did not acknowledge the adverse public health impacts arising from the large DCM air releases (and other environmental contamination) referred to in the assessment, or the relationship between the environmental contamination and consumer, industrial, and commercial uses of DCM-based paint strippers.	EPA/OPPT is assessing the risks of chemical uses that fall under the authority of the Toxics Substances Control Act (TSCA), which in this assessment is the use of DCM in paint strippers. EPA/OPPT is concerned about the human health hazards of DCM as documented in *section 3.3* and acknowledges that DCM is ubiquitously present in the environment with levels detected in drinking water, indoor environments, ambient air, groundwater and soil (*section 1.2.1*). Thus, EPA has taken regulatory actions through various statutory authorizes to reduce the environmental levels of DCM and its potential human health impacts (*section 1.2.4*). In addition, the Consumer Product Safety Commission, the Food and Drug Administration, the Occupational Safety and Health Administration (OSHA) and some U.S. States have also taken regulatory action to reduce exposures to DCM (*Appendix A*).
11	EPA/OPPT should move the biomonitoring discussion to the exposure section.	EPA/OPPT retained the discussion of the biomonitoring data in *section 3.3* (Hazard/Dose-Response Assessment). No change was made in the final DCM risk assessment.

Occupational Exposure Assessment

Charge question 2-1: Please comment on the approach used, and provide any specific suggestions or recommendations for alternative approaches, models or information that should be considered by the Agency for improving its assessment of DCM workplace exposures, including specific citations (if available) of other data sources characterizing occupational inhalation exposures.

#	Summary of Peer Review and Public Comments for Specific Issues Related to Charge Question 2-1	EPA/OPPT Response
12	The literature search strategy should be described, and other references that may have relevant exposure data should be considered.	EPA/OPPT has added descriptions of the search strategy and quality criteria to *Appendix G.* EPA/OPPT reviewed all of the exposure-relevant references recommended by the public and peer review panel. A small amount of new data from Anundi et al., (1993), Anundi et al., (2000), Estill et al., (1996), and Hall et al., (1995), all within the ranges of our original data sets, has been added to the data sets in *Appendix G*. **References:** Anundi, H., S. Langworth, G. Johanson, M. L. Lind, B. Akesson, L. Friis, N. Itkes, E. Soderman, B. A. Jonsson, and C. Edling. 2000. Air and Biological Monitoring of Solvent Exposure During Graffiti Removal. Int Arch Occup Environ Health, 73(8), 561-569. Anundi, H., M. L. Lind, L. Friis, N. Itkes, S. Langworth, and C. Edling. 1993. High Exposures to Organic Solvents among Graffiti Removers. Int Arch Occup Environ Health, 65(4), 247-251. Estill, C. F., and A. B. Spencer. 1996. Case Study: Control of Methylene Chloride Exposures During Furniture Stripping. Am Ind Hyg Assoc J, 57(1), 43-49. Hall, R. M., K. F. Martinez, and P. A. Jensen. 1995. Control of Methylene Chloride—Furniture Stripping Dip Tank. Applied Occupational and Environmental Hygiene, 10(3), 188-195.

13	Several interrelated issues were raised by peer reviewers and public commenters regarding the worker inhalation monitoring data and its use in generating average daily concentrations (ADCs) and lifetime average daily concentrations (LADCs), a) More OSHA's Integrated Management Information System (IMIS) data should be used for estimating risks. b) Worker exposure trends due to OSHA's permissible exposure level (PEL) update in 1997 should be analyzed quantitatively, and data before 1997 should be excluded. c) Data presentation and transparency should be improved, including being more statistical, using central tendencies, or developing a probabilistic approach rather than using only composite ranges. d) Exposure controls are neglected.	EPA/OPPT further considered IMIS data and found no solid criteria for determining which IMIS data were associated with use of DCM-containing strippers. Thus, EPA/OPPT has concluded that the original preference for literature data over IMIS is valid. The risk assessment was revised to indicate that the IMIS data were generally excluded from use in risk estimation when literature monitoring data were available and preferred due to their known applicability to paint stripping (see *section 3.1.1.2* and *Appendix G, section G-2-2-1*), whereas IMIS exposure data may not be due to DCM-based strippers. However, the risk assessment used surrogate data from the IMIS database for the Art Restoration and Conservation industry in the absence of literature data for this industry. Further, EPA/OPPT analyzed the monitoring data and reported statistical values (e.g., arithmetic means and one 95th percentile), when possible, for several relevant industries, or midpoints of ranges when better statistical values could not be determined. These statistical improvements provided further support to using monitoring data over IMIS data. Regarding the PEL update, EPA/OPPT re-examined the IMIS data for the industries that were identified to do paint stripping. These IMIS data show that in some industries, exposure levels increased after the PEL update, and for other industries, exposure levels decreased after the PEL update. Overall, our analysis suggested that the 1997 PEL update did not have significant impacts on reducing the DCM air concentrations for these industries. Therefore, EPA/OPPT retained the monitoring data collected before the 1997 PEL update. This issue is discussed in *Appendix G*. Data presentation, transparency, statistics (including central tendencies), and exposure controls were particularly interrelated for assessment purposes. EPA/OPPT has improved upon the composite range approach by including statistical values (e.g., arithmetic means and one 95th percentile), where possible. When statistical values could not be provided, midpoints were provided as central tendency substitutes along with ranges. EPA/OPPT bolstered the data summaries in tables by including numbers of studies, numbers of data points, study dates, and data sources, along with adding more data to the summaries for completeness. Please refer to *Appendix G* for more information about these additions to the risk assessment.

		Moreover, there are no appropriate input distributions for most of the occupational exposure parameters. Thus, EPA/OPPT determined that a probabilistic approach is inappropriate for this assessment. The final DCM risk assessment included a scenario-based approach for the worker exposure assessment. EPA/OPPT developed exposure scenarios with and without respirators and using several exposure frequencies and worker lifetimes exposure durations of 20 yrs versus 40 yrs. EPA/OPPT used midpoints of frequencies and worker lifetime durations of exposures as substitutes for central tendencies. However, the relative prevalence of respirator use and central tendencies of frequencies and working lifetimes is unknown. Readily available data were insufficient for quantifying exposure impacts due to other exposure control measures such as local ventilation, although anecdotal examples of such controls were included in *Appendix G,* where available.
14	The census data are too weak to be used to calculate worker population estimates.	EPA/OPPT considered other data sources such as EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) for Paint Stripping. NESHAP data were usable for postulating estimates of the total population of workers involved in the paint stripping operations for all industries combined. Also, the NESHAP data were used to estimate a range of the total number of workers directly exposed in small shops (< 10 workers). Please see *Appendix F* for further discussion. EPA/OPPT also made revisions to *Appendix F* to clearly show the estimates of number of workers per shop in each of the industries.
15	EPA/OPPT should include more information on label instructions, common industry practices, and high-end or extremes in stripper use.	*Appendices F* and *G* incorporated additional information about common industry practices when available. EPA/OPPT could not find data on high-end and extreme stripper use rate data. Information on labeling instructions was not incorporated in the final risk assessment because such instructions would be anecdotal. With the exception of respirator use, the inclusion of all of these types of information would not impact exposure estimates used in the risk analyses. The expected prevalence of respirator use was discussed qualitatively in *Appendix G*.

Consumer Exposure Assessment

Charge question 3-1: Please comment on the approach used and provide any specific suggestions or recommendations for alternative approaches, models, or information that should be considered by the Agency in developing the exposure assumptions and estimates for the consumer use of DCM-based paint strippers and for the bystander/non-users (e.g., children, women of childbearing age). As part of the review, please comment on the strengths and weaknesses of the evaluation of different exposure scenarios and the choice of assumptions/input parameters for generating central tendency and upper-end DCM air concentrations.

#	Summary of Peer Review and Public Comments for Specific Issues Related to Charge Question 3-1	EPA/OPPT Response
16	A public comment stated that all the exposure scenarios were indoor and asked whether there was consideration of product use outside.	EPA/OPPT focused the risk assessment on the indoor residential use of DCM-based paint strippers. The assessment did not consider the outdoor use of these products.
17	A panelist suggested expanding the paint stripping protocol description and insert same in body of document.	*Section H-3* of *Appendix H* discusses how labeling instructions guided the selection of input parameters or assumptions about the stripping sequence, ventilation conditions (i.e., open windows) and user location during wait period. Details such as effects of container left open, methods to loosen paint, and cleanup procedures were not incorporated in the consumer modeling.
18	Several peer reviewers suggested that a larger surface area or multiple pieces of furniture for longer stripping periods be considered as exposure scenarios. They also suggested adding extra scenarios with closed windows, which would have lower air exchange rate (ACH). It was also recommended that stripping periods have more documentation. A public commenter stated that EPA/OPPT overstated the risk of exposure via worst case (bathroom) scenario assessment.	*Appendix H, section H-3*, discusses the unlikely scenario of stripping multiple pieces of furniture. It also states that surface areas were selected so that the resulting product masses used in the modeling scenarios corresponded approximately to central (near the median) and upper-end (near the 80th percentile) estimates for the amount of paint stripper used per event from a nationwide survey by CPSC (1992). CPSC (1992) reported larger percentile amounts, but given that the amounts used in the assessment indicate health concerns, more conservative modeling is not necessary. This is also a reason why modeling with lower ventilation is not needed, although such scenarios may occur they would produce even higher exposure estimates. Language has been added *in section 3-2 and Appendix H (section H-3)* to state that all of the scenarios, but the bathroom scenario, were considered plausible and that application time was derived from EPA (1994). Moreover, the choices for the consumer scenario parameters, with the exception of those for the bathroom scenario, were supported by label suggestions for

		ventilation (open windows) and/or by information on user behavior in CPSC (1992), Pollack-Nelson (1995) and Riley (2001). The bathroom scenario was linked to worst-case exposure conditions based on a fatality case resulting from overexposure to DCM during a bathtub refinishing project. Please refer to *Appendix H, section H-3*, for more information. **References:** EPA (U.S. Environmental Protection Agency). 1994. *Consumer Exposure to Paint Stripper Solvents*. Office of Pollution Prevention and Toxics, Washington, DC. CPSC (Consumer Product Safety Commission). 1992. *Methylene Chloride Consumer Products Use Survey Findings*. Prepared by L. Boast from Abt Associates, Inc., for the U.S. Consumer Product Safety Commission, Bethesda, MD. Pollack-Nelson, C. 1995. *Analysis of Methylene Chloride Product Labelling*. Ergonomics, 38(11), 2176-2187. Riley, D. M., B. Fischhoff, M. J. Small, and P. Fischbeck. 2001. *Evaluating the Effectiveness of Risk-Reduction Strategies for Consumer Chemical Products*. Risk Analysis, 21(2), 357-369.
19	Peer reviewers suggested comparing modeling results to DCM monitoring data reported in other studies, and also investigating the low 33% release rate of the brush-on product.	EPA/OPPT compared the consumer modeling results with monitoring-based exposure estimates in *Appendix H, section H-5*. The low release rate (33%) for the brush-on product was associated with the presence of a vapor retardant. This is discussed in *Appendix H, sections H-1-1-2* and *H-1-1-4*.
20	A peer reviewer recommended the following: • a correction to the near field (source cloud) assessment for the bathtub scenario; • incorporation of a near field approach for the inhalation modeling; • expansion of the descriptions about the Multi-Chamber Concentration and Exposure Model (MCCEM).	EPA/OPPT corrected the source cloud (near field) mathematical error and associated exposure estimates for the bathtub stripping scenario. However, near field modeling was not considered appropriate for the workshop consumer exposure scenarios. Work areas within a workshop are less likely to promote localized accumulation of DCM vapors when compared to confined work areas such as a bathtub. Thus, the workshop scenario was modeled as a well-mixed zone. *Appendix H*, *section H-3*, discusses further support for this approach.

21	A peer reviewer commented that a probabilistic approach could prove much more informative than the varying point estimate approach used for consumer inhalation assessment.	*Appendix H*, *section H-3*, presents details about the modeling approach and the rationale for selecting the input parameters and assumptions supporting the consumer inhalation scenarios. EPA/OPPT believes that the consumer modeling approach is appropriate to evaluate DCM exposures to paint strippers in residential settings and thus a probabilistic approach was not necessary. MCCEM is a Tier 2 exposure model.
22	A peer reviewer commented that the draft DCM risk assessment did not address aversive worker/consumer behaviors.	EPA/OPPT believes that aversive behavior due to odor is not considered health protective. The ability to detect odors varies by individual, and tolerance to odors can be developed over time. Human variability in odor detection and tolerance may have contributed to the reported fatalities related to overexposure to DCM during bathtub refinishing projects.
23	Public commenters suggested more justification for use of the MCCEM model.	*Section 3.2.2* provides additional information about the MCCEM model, including a description of the model features that led us to select it for the consumer modeling approach.
24	Public commenters recommended that Figure 3-4 should be moved to follow descriptions of the scenarios, instead of before the scenario descriptions.	EPA/OPPT performed the sensitivity analysis before running the model for the different consumer exposure scenarios. This allowed us to develop the exposure scenarios by determining which parameters had the most influence over the exposure estimates. Thus, the discussion of the sensitivity analysis (*section 3.2.4.1, Figures 3-3* and *3-4*) was placed before the presentation of the modeling scenarios (*section 3.2.4.2*).
25	Public commenters stated that the label “user personal concentration” in Fig 3-1 is confusing, as it implies a personal air monitor.	EPA/OPPT has removed the confusing language from *Figure 3-1.* The term “personal” was used in the draft DCM risk assessment to indicate the modeled DCM air concentration(s) that the user would be exposed to in either the product use area or the rest of the house, depending on the user activity patterns. The user exposure may be to a combination of concentrations, as indicated in *Appendix H, section H-4*.
26	A public commenter suggested that EPA/OPPT should discuss the impact of variability of measured emission results on model estimates. Evaluation of the emission chamber test data showed that the variability in the emission values was greater for the brush-on DCM product than that reported for the spray-on DCM product.	As discussed in *Appendix H, section H-1-1-1*, the intermediate emission results for the monitored brush-on product were used for modeling, thus minimizing the effect of the larger variability of emission values for the brush-on product when compared to that reported for the spray-on product.

27	A public commenter suggested that text in the consumer exposure sections should be rewritten to clearly distinguish which variables were influenced by the sensitivity analysis and which were not.	EPA/OPPT clarified text in *sections 3.2.3* and *3.2.4.1* about the sensitivity analysis.
28	A public commenter suggested more transparency for the MCCEM modeling—EPA/OPPT should provide complete documentation for the MCCEM inputs used to evaluate each scenario.	*Appendix H* provides detailed documentation on the modeling approach, input parameters/assumptions and exposure calculations for the model outputs. Information about the MCCEM input parameters is specifically found in *Appendix H, section H-3.*
29	A public commenter asked why the interzonal air flows were higher than the air flow between workshop and outdoors. The commenter assumed that the door(s) between zones were closed, so the interzonal flow should be lower.	The interflow airflow rate was estimated using an algorithm derived from empirical ventilation data collected in over 4,000 U.S. residences by the perfluorocarbon tracer (PFT) technique (EPA, 1995). In the analysis, the doors between residential zones were generally considered to be open. This is discussed in *Appendix H, section H-3* (*Airflow Rates and Volumes*). **Reference:** EPA (U.S. Environmental Protection Agency). 1995. *Estimation of Distributions for Residential Air Exchange Rates*. Office of Pollution Prevention and Toxics, Washington, DC. http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=910063GS.txt.
30	A public commenter stated: “EPA acknowledges that it is unclear whether central-tendency, as well as high-end exposures, fall within the range of exposures estimated in the assessment”	Central-tendency and upper-end values are by definition within the range of exposures, as described in footnotes 10 and 11 in *section 3.2.4.2* and *section 3.5.2 (Uncertainties in the Consumer Exposure Estimates)*.
31	Peer reviewers suggested that there should be more explicit consideration of child bystanders, who are likely to have different activity patterns and be closer to the ground, which may affect their inhalation exposure levels.	EPA/OPPT estimated exposures to product users and bystanders based on the predicted DCM air concentrations in the different residential zones (i.e., room of use, rest of the house). The zones were assumed to have well-mixed DCM air concentrations. Bystanders, who are individuals of any age (e.g., children, adults, the elderly), were assumed to be in the rest of the house during product use. The rest-of-the-house zone, where bystanders would be located, was assumed to have a well-mixed DCM air concentration. In this case, the

		exposed individual height is not relevant. The Executive Summary, *Sections 1.3.3, 3.4.1* and *3.5.3.2* identify child bystanders as a potential human population exposure to DCM from the use of paint strippers.
32	A peer reviewer stated that there was a lack of justification for exposure time during application.	*Appendix H, section H-3* indicates that the application and scrape times were deduced from the MRI chamber study (EPA 1994). **Reference:** EPA (U.S. Environmental Protection Agency). 1994. *Consumer Exposure to Paint Stripper Solvents*. Office of Pollution Prevention and Toxics, Washington, DC.
33	A peer reviewer recommended that the current modeling results should be compared to the EPA 1994b report's monitored values and also data from other studies (EC, 2004 and van Veen et al 2002).	*Appendix H, section H-1* provides a discussion about the monitoring studies and *section H-5* provides a comparison of monitoring and modeling results.
34	A public commenter asked why concentrations associated with upper-end user scenarios in Table 3-7 were lower than those associated with upper-end non-user (bystander) scenarios.	Table 3-7 labels the scenarios as upper-end for the user or non-user based on changes in parameters shown to be more sensitive for the user or non-user. Table 3-7 showed that the user exposure for Scenario 3 (brush-on), where the most sensitive parameters were made upper-end for both the user and the bystander, was higher than the user exposure for Scenario 2, where the most sensitive parameters were made upper-end only for the user. This is also seen when comparing the spray-on scenarios 5 and 6. The reason for this observation has to do with the effect of using a higher chemical mass and a lower air exchange rate (ACH) in the rest of the house for Scenarios 3 and 6. Changes in both chemical mass and ACH parameters are more influential than changes in only user location from workshop to the rest of the house, as occurred in Scenarios 2 and 5 (upper-end for user). Consequently, the user concentrations for Scenarios 3 and 6 are higher than those for Scenarios 2 and 5, respectively. Note that the user location was the most

		sensitive parameter for short exposures, but much less sensitive at longer exposure times. Tables 3-5 and 3-6 have been revised to clarify this issue.
35	EPA/OPPT received comments about the source cloud approach used in the bathroom scenario. It was suggested to model the bathroom scenario as a single zone and compare the results with those obtained with the source cloud approach. As maximum exposure concentrations were predicted for the bathroom scenario, additional sensitivity analysis, especially with regard to the localized source cloud, would be appropriate. In addition, the near-field/far-field (NF/FF) model was suggested for the bathroom scenario, instead of the current source cloud approach. The NF/FF model is commonly used to estimate exposures in the breathing zone for a worker in close proximity to a volatilizing source.	EPA/OPPT believes that the source cloud modeling is more appropriate than the single-zone modeling for the bathroom scenario. The user must work not only adjacent to, but partially within the concave bath tub. Also, ventilation characteristics are different for a semi-enclosed space such as a bathtub when compared to the surrounding room. Unlike some of the workshop scenarios, the user is expected to be outside the bathroom during the wait period. *Figure H-15* in *Appendix H, section H-4-3* compared the DCM source cloud concentration to those in the bathroom zone and the rest of the house. The source cloud concentration (line Z1) was higher than the bathroom zone concentrations (line Z2). These results show that the source cloud approach captured the differences in air concentrations within the bathroom (near the bathtub versus the rest of the bathroom) and the rest of the house. EPA/OPPT expanded the discussion of the source cloud approach in *Appendix H, section H-3.* EPA/OPPT did not conduct a sensitivity analysis for the bathtub stripping scenario because the model scenario recreated exposure conditions related to a fatality case associated with the use of a DCM-based stripper in a bathtub refinishing project (CDC, 2004). EPA/OPPT estimated the DCM air concentrations in the rest of the house while such worst-case exposure conditions occurred in the bathroom. **Reference:** CDC (Centers for Disease Control and Prevention). 2012. *Tub Refinisher Died Due to Methylene Chloride Overexposure While Stripping a Bathtub*. Michigan case report: 10M1013. Atlanta, GA. http://www.cdc.gov/niosh/face/stateface/mi/10MI013.html.
36	A public commenter suggested changing "peak or maximum TWA" to "maximum time period TWA."	Peak and maximum TWA were used interchangeably; the assessment has been edited to use maximum TWA. This change is exemplified in *Table 3-7*.

Hazard and Dose-Response Assessments

Charge question 4-1: Please comment on EPA's use of the acute PODs that were identified from the technical documents supporting the Cal EPA REL, SMAC and AEGL derivations. As part of the review, please provide your input on the appropriateness of the approach, including its underlying assumptions, strengths and weaknesses. Please provide any specific suggestions or recommendations for alternative approaches that should be considered by the Agency in characterizing the acute inhalation risks. Please provide relevant data or documentation and rationale for including other studies and endpoints for consideration.

Charge question 4-2: Please comment on EPA's choice of PODs and IUR for evaluating the non-cancer and cancer risks, respectively for chronic exposures to DCM-based paint strippers. As part of the review, provide your input on the appropriateness of the approach, including its underlying assumptions, strengths and weaknesses. Please provide any specific suggestions or recommendations for alternative approaches that should be considered by the Agency in characterizing the chronic inhalation risks to workers. Please provide relevant data or documentation and rationale for including other studies and endpoints for consideration.

#	Summary of Peer Review and Public Comments for Specific Issues Related to Charge Questions 4-1, and 4-2	EPA/OPPT Response
37	Peer review and public comments indicated that the application of the California's acute reference exposure level (REL) and acute exposure guideline levels (AEGLs) was confusing in the draft DCM risk assessment and should be clarified. AEGL-1, but not AEGL-2 values, should be used in the acute inhalation risk assessment. Other comments recommended using AEGL-1 values over the California's acute REL. There was confusion of why the SMACs were used in the assessment if they are not safe values and intended for spacecraft operations. Also, commenters suggested selecting an acute POD for the acute risk assessment instead of having multiple approaches.	The acute inhalation risk assessment used the hazard and dose-response information supporting the derivation of DCM's *Spacecraft Maximum Allowable Concentrations (SMAC)* (NRC, 1996), the *California's Acute Reference Exposure Level* (REL) (OEHHA, 2008), and the *Acute Exposure Guideline Levels* (AEGL) (NAC, 2008). These assessments were developed by reputable organizations and subjected to a peer review process. *Appendix I* of the final DCM risk assessment briefly summarizes the guidelines supporting the development of these assessments. EPA/OPPT preferred the SMAC hazard value [or point of departure (POD)] over the California's acute REL POD as the health protective hazard value used in this assessment. The SMAC POD was based on multiple human observations reporting increased carboxyhemoglobin (COHb) levels after DCM exposure, coupled with the knowledge of what would be considered a no-observable-adverse effect level (NOAEL) based on the extensive carbon monoxide (CO) database (NRC, 1996). However, the California's acute REL POD was used to estimate risks for occupational scenarios since an 8-hr SMAC POD was not available for the risk calculations. Although AEGLs are intended for emergency response activities and are not safe levels, the AEGL PODs were used in this assessment to evaluate acute risks for non-disabling (AEGL-1) and incapacitating (AEGL-2) effects following DCM inhalation exposure. EPA/OPPT believes that inclusion of AEGL PODs in the assessment is

	A peer reviewer commented on EPA/OPPT's reliance on previous hazard/dose response assessments instead of conducting its independent review of the data.	reasonable based human fatalities recently reported in bathtub refinishing projects using DCM-based paint strippers. The selected PODs (AEGL-1 and -2) are below the threshold for lethality and intend to evaluate whether the occupational and consumer DCM air concentrations are high enough to induce non-disabling and incapacitating effects prior to the occurrence of death. These clarifications about the acute PODs and why EPA/OPPT preferred certain values over others are discussed in *section 3.3.1*. **References:** NRC (National Research Council). 1996. *Spacecraft Maximum Allowable Concentration for Selected Airborne Contaminants: Methylene Chloride (Volume 2)*. National Academy Press, Washington, DC. http://www.nap.edu/catalog.php?record_id=5170. OEHHA (Office of Environmental Health Hazard Assessment). 2008. Acute reference exposure level (REL) and toxicity summary for methylene chloride, Sacramento, CA. http://oehha.ca.gov/air/hot_spots/2008/AppendixD2_final.pdf#page=187. NAC (National Advisory Committee). 2008. *Interim Acute Exposure Guideline Levels (AEGL) for Methylene Chloride*. Washington, DC. http://www.epa.gov/oppt/aegl/pubs/methylene_chloride_interim_dec_2008_v1.pdf.
38	Acute and chronic case reports and epidemiological studies are missing from the hazard/dose-response assessment. Also, cancers following DCM exposure have not been reported in humans.	*Section 3.3.2.2* of the final DCM risk assessment briefly summarizes the human toxicity data following acute exposure to DCM. *Section 3.3.2.3.2* lists several occupational studies providing evidence for an association between cancer and DCM exposure.
39	Peer review and public commenters asked EPA/OPPT to consider adding a number of references to the hazard/dose-response assessment.	EPA/OPPT reviewed all of the suggested and incorporated MacIsaac et al. (2013). **Reference:** MacIsaac, J., R. Harrison, J. Krishnaswami, J. McNary, J. Suchard, M. Boysen-Osborn, H. Cierpich, L. Styles, and D. Shusterman. 2013. *Fatalities Due to Dichloromethane in Paint Strippers: A Continuing Problem*. American Journal of Industrial Medicine, 56, 907-910.

40	CNS toxicity studies are not described in the assessment.	*Sections 3.3.2.2* and *3.3.2.3.1* summarize the neurological effects observed following acute or chronic exposure to DCM. In addition, the acute PODs were based on neurological effects in humans (*section 3.3.1.3* and *Appendix I*).
41	Unclear description of acute study reporting immunological effects	*Section 3.3.2.2* briefly discusses the potential immunotoxic effects of DCM as reported by Aranyi et al. (1986). This study exposed CD-1 mice to 100 ppm DCM for 3 hrs and reported localized immunosuppressive effects in the lung. Aranyi et al. (1986) is discussed in the DCM IRIS assessment, *Chapter 4.*
42	Public comments noted a series of inaccuracies/deficiencies in the acute (section 3.3.3) and chronic (section 3.2.3) sections of the draft DCM risk assessment. Most of the comments were about missing references and incorrect statements that needed to be relocated to other sections.	When appropriate, EPA/OPPT made appropriate revisions to the acute and chronic hazard sections, including the insertion of missing references and relocating statements to other sections. See *section 3.3.2.2* and *3.3.2.3* of the final DCM risk assessment.

Risk Characterization

Charge question 5-1: Please comment on the assumptions, strengths and weaknesses of the MOE and HQ approaches used to estimate the acute non-cancer risks to consumers of DCM-based products, including bystanders/non-users (e.g., children, women of childbearing age). Please also comment on the selection of composite uncertainty factors that were used as benchmark MOEs to determine the acute risks.

Charge question 5-2: Please comment on the assumptions, strengths and weaknesses of the MOE approach used to estimate the chronic non-cancer risks for workplace exposures. Please also comment on the selection of composite uncertainty factors that were used as benchmark MOEs to determine the chronic risks.

Charge question 5-3: Please comment on the assumptions, strengths and weaknesses of the cancer estimation risk approach used for the workplace exposures.

Charge question 5-4: Please comment on whether the risk assessment document has adequately described the uncertainties and data limitations in the methodology used to assess risks to allow the EPA to reduce risks to human health from DCM. Please comment on whether this information is presented in a transparent manner.

#	Summary of Peer Review and Public Comments for Specific Issues Related to Charge Questions 5-1, 5-2, 5-3 and 5-4	EPA/OPPT Response
43	A peer reviewer noted that a total UF of 30 was applied to the non-cancer chronic POD in the DCM IRIS assessment, but a total UF of 10 was used in the EPA/OPPT risk assessment.	The final DCM risk assessment uses a total UF of 10 as the benchmark margin of exposure (MOE) to evaluate non-cancer chronic risks for the occupational scenarios (*section 3.3.1.2.2, Table 3-8*).
44	Peer review and public comments suggested using occupational values (e.g., OSHA STEL) to evaluate occupational risks.	EPA/OPPT did not use occupational values for risk estimation as they are generally not the most health protective values.
45	The draft DCM risk assessment reported most of the risk estimates as MOEs, but risks based on the AEGL PODs were reported as hazard quotients (HQs). The risk estimation approach should be harmonized.	The final DCM risk assessment is using only MOEs to estimate acute and chronic risks (*section 3.4*).
46	Non-cancer acute risks should be estimated for occupational exposure scenarios.	Non-cancer acute risks were included in the final DCM risk assessment (*sections 3.3.1.3* and *3.4.2.2, Table 3-11*).
47	EPA/OPPT should address acute risks for incapacitating (AEGL-2 effects).	EPA/OPPT is concerned about those consumer and occupational scenarios reporting risks for incapacitating (AEGL-2 effects) and will consider the risk findings during risk management.

48	EPA/OPPT is using graphs that improperly compare the predicted time-varying DCM exposure concentrations for consumer scenarios with various acute toxicity values (e.g., AEGL-1, AEGL-2 and AEGL-3, California's acute REL and SMAC). These comparisons were shown in Figures 3-5 through 3-8 in the draft DCM risk assessment.	EPA/OPPT deleted the graphs from the final risk assessment.
49	The draft DCM risk assessment stated that the acute risks for neurotoxicity may be underestimated for younger individuals based on a hazard value derived from neurotoxicity in adults. This statement was included section 3.5.3 of the draft DCM risk assessment.	EPA/OPPT made revisions to the statement in *section 3.5.3.2.1* to acknowledge that the acute risks may be under- or overestimated for younger individuals when using a hazard values based on neurotoxicity in adults.
50	The chronic non-cancer and cancer risks are underestimated because inhalation intake rates were not incorporated into the calculations of average daily concentrations (ADCs) and lifetime average daily concentrations (LADC). EPA/OPPT should revise the ADC/LADC calculations to account for inhalation intake rates.	EPA/OPPT used the air concentration in air in the ADC/LADC calculations since the amount of chemical being inhaled is not a simple function of inhalation intake rates and body weight. Instead, the interaction of the inhaled contaminant with the respiratory tract is affected by factors such as species-specific relationships of exposure concentrations to deposited/delivered doses and physiochemical characteristics of the inhaled contaminant (EPA, 2009). EPA guidance recommends using the concentration of the chemical in air as the exposure metric when estimating inhalation risks (EPA, 2009). **Reference:** EPA (U.S. Environmental Protection Agency). 2009. *Risk Assessment Guidance for Superfund. Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)*. EPA-540-R-070-002. Office of Superfund Remediation and Technology Innovation, Washington, DC. www.epa.gov/oswer/riskassessment/ragsf/pdf/partf_200901_final.pdf.
51	EPA/OPPT should avoid using the term "level of concern" when referring to the total UF used to interpret MOE values.	The final DCM risk assessment refers to "benchmark MOE" to the total UF used to evaluate MOE values.
52	Discussion of uncertainties and limitations should be improved for the exposure, hazard/dose-response and risk characterization assessments. Directional impact on risk should be included, and the discussion should be more complete and robust.	EPA/OPPT determined gaps in the discussion and completed substantial improvements to *section 3.5* (*Discussion of Key Sources of Uncertainty and Data Limitations*). In some cases, the impact on risk estimates was discussed (e.g., Table 3-34).

53	The draft DCM risk assessment did not evaluate the cumulative exposure from other uses of DCM around the home. This is another potential source of risk under-prediction that was not characterized in the draft DCM risk assessment.	The final DCM risk assessment acknowledged this source of uncertainty in *section 3.5.4*.
54	Several comments addressed the inclusion and exclusion of the 3x database uncertainty factor.	While the IRIS DCM assessment includes a 3x database uncertainty factor for the chronic noncancer RfC it was not included in the benchmark margin of exposures evaluated for chronic duration scenarios for workers. It is noteworthy that the MOE approach is endpoint specific, applied for a specific duration and not intended to be protective for other endpoints which have limited data. Data gaps in the overall hazard database are discussed in the uncertainty section (*section 3.5.3*). There are a lack of data about developmental neurotoxicity, longer term exposures and resulting neurotoxicity and immunotoxicity. These endpoints do not have sufficient data for quantification and remain uncertain.

Other Public Comments

#	Summary of Other Public Comments	EPA/OPPT Response
55	EPA/OPPT should address OSHA authorities to regulate occupational exposures.	EPA/OPPT will consult with other federal agencies, including the Occupational Safety and Health Administration (OSHA), when discussing risk management options for DCM exposures associated with paint stripping.